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Guohua Chen

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/606,969	Applicant(s) CHEN ET AL.	
	Examiner Eric E. Silverman, PhD	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-105 is/are pending in the application.
 4a) Of the above claim(s) 61-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-60 and 105 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>16-10-05, 4-12-04, 1-23-06</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1 – 105 are pending in this action.

Election/Restrictions

Applicants' response to Election/Restriction requirement, filed 4/05/2006, has been received. Applicants elected Group I, claims 1 – 60 and 105. Although Applicants' claimed to elect with traverse, no error in the Election/Restriction requirement was alleged in the response. As such, the election is being treated as having been made **without traverse**. Claims 61 – 104 are withdrawn from consideration as drawn to non-elected inventions.

Double Patenting

Claim 105 of this application conflict with claim 79 of Application No. 10/701,939. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in

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scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 105 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 79 of copending Application No. 10/701,939. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 10, 14 – 20, 27 – 30, 35 – 46, 50, 53, 57 – 60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 7 – 9, 15, 18 – 20, 26, 27, 32 – 34, 40, 43 – 45, 49, 50, 54, 56, 57, 63, 66 – 68 of Application Serial Number 10/701,939. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the limitations of instant claims and that of copending claims is that copending claims require a specific delivery duration for the composition, whereas instant claims are generic to this feature. As such, copending claims represent a species of instant generic claims, and as such render instant claims obvious in their entirety.

This is a provisional rejection because the copending claims have not yet been patented.

Claims 1 – 9, 15 – 17, and 24 – 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 6, 8, 12, 13, 14, 17 – 20, and 22 of copending Application No. 10/857,609. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between instant claims and copending claims is that copending claims recite the duration over which the beneficial agent is released, whereas instant claims are generic to this feature. As such, copending claims are a species that falls within the genus of instant claims, thus rendering instant claims obvious in their entirety.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 60 and 105 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 27, 28, 29, 57, 59, and 105 each recite one or more of the following terms, which render the claims indefinite. The term “low molecular weight” renders the claims indefinite when the claim does not also specify what molecular weight is considered “low”. The phrase “miscibility in water of less than or equal to 7%” renders the claim indefinite. The term “miscible” is applied to two liquids that are soluble in each other in all proportions. Thus, by definition, miscibility cannot be described in this manner. For the purpose of compact prosecution, Examiner will interpret this limitation to mean “solubility in water of ~~less~~^{at} least than or equal to 7%”. These claims also recite an “amount sufficient to plasticize the polymer and form a gel therewith”. It is not clear how much solvent would be “sufficient” as claimed. For the purpose of compact prosecution, Examiner will interpret this limitation to require the presence of a solvent, as claimed. Clarification is requested.

The remaining claims are rejected under this statute at least for depending on one or more of the claims discussed above without remedying all of these issues.

Claims 4, 5, 8, and 41 are indefinite for the recitation of “lower alkylene”. Without a specific limiting definition in the specification, the artisan would not be certain as to how many carbon atoms could constitute a lower alkylene, and thus would not be able to understand the metes and bounds of the claimed invention.

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Regarding claims 7 – 9 and 44 – 46, these claims are not clear in light of the claims on which they depend. Claims 2 and 29 require that the solvent be an aromatic alcohol, yet instant claims require an ester of an aromatic acid in addition thereto. As such, these claims do not seem to further limit the claims on which they depend. Claims 9 and 46 are being interpreted to mean that one of the esters recited therein is required to be mixed with the aromatic alcohol recited in claims 8 or 45, respectively. Clarification is requested.

Regarding claims 15, 17, and 35, these claims are indefinite for the recitation of a “lactic acid based polymer”. It is unclear what requirements a polymer would need to fulfill to be “lactic acid based”; for instance, would the polymer have to contain lactic acid in the polymer backbone, and if so how much? (would a copolymer with only 1% lactic acid comply? 25%?), or would it be sufficient for the polymer to have lactic-acid pendant groups, and if so, how many? Would a polymer that comprises a monomer or pendant group that is synthesized from lactic acid meet the requirement? Absent a specific, limiting definition in the specification, the artisan would not be clear as to what this term comprises, and as such would be unable to determine the metes and bounds of these claims.

Claims 21, 22, 51, and 52 recite “metabolites, analogs, derivatives, and fragments thereof”. Absent a limiting definition in the specification, the artisan would not be certain what is encompassed by these terms, and thus would be unable to discern the metes and bounds of the claimed invention.

Claims 24 and 54 recite the limitation "viscous gel" in claim 21 and 51, respectively. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 24, 27 – 32, 34 – 47, 49 – 54, 57 - 60, and 105 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by WO 02/38185 A2, of record.

The '185 reference discloses a composition comprising a polyester, an organic solvent, and a beneficial agent (claim 1). The composition is taught to be injectable (example 3) The polymer can be a poly(lactide-co-glycolide) (claim 4), and is present in amounts commensurate with instant claims (claim 5, examples 2 and 3). The molecular weight is also commensurate with that of instant claims, for example, 6,000 daltons (example 2). The solvent may be benzyl alcohol, benzyl benzoate, or a mixture thereof (claim 7), and is present in amounts commensurate with that of instant claims (claim 11, examples 2 and 3). Although the ratio of the mixture is not specified, instant claim 47 is rejected because the recited range of ratios, "about 1% to about 99%", is broad enough to read on any mixture of these two components. The beneficial agent is taught to be in a suspension (examples 2 and 3), which is understood to mean that it is in the form of dispersed particles. In example 3, an additional PEG-poly(lactide-co-glycolide) block

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copolymer is added. This is deemed to be a solubility modifier, as required by instant claim 20. The beneficial agent is an antihyperalgesic (page 16), which satisfies the limitations of claims 21, 22, 51, and 52, and is present in amounts commensurate with that of instant claims (examples 2 and 3). The reference further teaches a kit (claims 38 – 45), containing the composition of the invention, commensurate in scope with instant claims in that the beneficial agent is in a separate container from the other agents.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/38185 A2, of record.

Some of the teachings of the '185 reference are discussed above. The reference also teaches that the molecular weight of the polymer may be 4,000 to 45,00 daltons (claim 6), and in exemplary embodiments, is 6,000 daltons. The reference also teaches that changing the molecular weight of the polymer is a means to alter the release profile of the composition, and further teaches how to vary the molecular weight of polymers (pages 13 – 14).

As such, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use a molecular weight of 5,000 daltons, since the prior art recites ranges of molecular weights that include the claimed molecular weight, and further teaches specific molecular weights that are similar enough to that claimed to be suggestive thereof. The difference between the recitation of instant claim and the teaching of the reference constitutes merely a routine optimization of molecular weight, which could be accomplished without undue experimentation. The artisan would be able to judge the proper release profile based on various conditions commonly dealt with in the art, such as the drug being used, type and severity of the medical condition being treated, and the like. The motivation to make this modification is to obtain the release profile that would best treat the patient and condition of interest. Since the reference provides the technical knowledge needed to control the release profile, and is suggestive of the molecular weight claimed, the artisan would enjoy a reasonable expectation of success.

Claims 25, 26, 48, 55, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/38185 A2 in view of WO 00/74650 A2.

The teachings of the '185 reference are discussed above.

The '185 reference is silent regarding particle size and does not teach the use of ethyl benzoate.

The '650 reference teaches injectable gel depot compositions (page 1) comprising particles (examples 1 – 3). The particles are taught to be between 40 and 200 microns, specifically 65, 85, 80, 76, and 74 microns (example 3). The particles advantageously comprise stearic acid as a “bulking agent” to control the microenvironment thereof (page 42). Further, the '650 reference teaches that ethyl benzoate and benzyl benzoate are both useful as solvents in gel compositions to achieve a low initial burst of drug release (page 42 and figure 6 and descriptions thereof).

As such, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to make particles of the drug and a bulking agent, and to make the particles the size taught by the '650 reference. The motivation to do so is the teachings of '650 that advantageous effects, specifically control of the microenvironment, can be achieved.

It would be further obvious to use a combination of ethyl benzoate and benzyl benzoate as the solvent. It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As

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shown by the recited teachings, instant claims are no more than the combination of known solvents for gel delivery systems. It therefore follows that the instant claims define prime facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). With regard to the amount of each, this is a matter of routine optimization. Since the two solvents yield roughly the same effect (figure 6 of '650), the artisan would expect to achieve the taught low initial burst of drug with any combination of the two.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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